K113221

510(k) Summary of NAMSA Biological Indicator Spore Strips

APR 2 7 2012

Submitter:

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Prepared on: October 28, 2011

Device Name: NAMSA Biological Indicator Spore Strips

Classification: Class II Medical Device, FDA Product Code FRC, General Hospital

Predicate Devices: (Legally Marketed) NAMSA Biological Indicator Spore Strips

Predicate Device 510(k) Number: K912796, K020026 and K050591

Description: The NAMSA Biological Indicator Spore Strip consists of a 1.25" x 0.25" filter paper strip inoculated with either a single species (*Geobacillus stearothermophilus* ATCC® 7953, 10^5) or dual species (*Geobacillus stearothermophilus* ATCC® 7953, 10^5 and *Bacillus atrophaeus* ATCC® 9372, 10^6) bacterial spores. The strip is packaged in a 30# glassine pouch.

Operational Principles: The NAMSA Biological Indicator Spore Strip (single species *Geobacillus stearothermophilus* ATCC® 7953, or dual species *Geobacillus stearothermophilus* ATCC® 7953 and *Bacillus atrophaeus* ATCC® 9372) is intended for use in testing the efficacy of steam sterilization for single species and steam and ethylene oxide sterilization for dual species.

Performance characteristics are established in accordance with ANSI/AAMI/ISO 11138 and USP for 121°C steam gravity displacement for 30 minutes and ethylene oxide at 600 mg/L, 60% RH and 55°C for 2 hours, 10 minutes.

The media containing the spore strip should be incubated at the organism's growth temperature. Media should be monitored daily for visible signs of growth and results recorded.

When standard media is utilized, incubate strips for a minimum of 7 days. Growth will be indicated by the presence of turbidity. A reduced incubation time of 24 hours for steam sterilization has been validated when the Biological Indicator Spore Strips are used in conjunction with Tryptic Soy Broth (TSB) modified with Bromocresol Purple.

Statement of Similarity to Legally Marketed Predicate Device:

The NAMSA Biological Indicator Spore Strip has the following similarities to the legally marketed Pre-amendment Biological Indicator Spore Strip:

- Same indication for use
- Incorporate the same materials
- Have the same shelf life, and
- The same materials for packaging

In summary, the data provided demonstrates NAMSA Biological Indicator Spore Strip are substantially equivalent to the predicate device.

Description of Testing: Per FDA recognized consensus standards and guidance documents, testing was performed for steam for single specie spore strips and steam and Ethylene Oxide (EO) sterilization processes for dual species. Multiple lots of NAMSA Biological Indicator Spore Strips were utilized.

- Total Viable Spore Count
- Resistance Characteristics Studies including D-value, Z-value and Survival/Kill Windows
- Carrier and Primary Packaging Materials Evaluation
- Holding Time Assessment
- Recovery Protocols – Reduced Incubation Time Studies
- Medium Suitability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Julie Wheeler
General Manager
North American Science Assoc, Incorporated
6750 Wales Road
Northwood, Ohio 43619

APR 2 7 2012

Re: K113221
Trade/Device Name: NAMSA Biological Indicator Spore Strip
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: II
Product Code: FRC
Dated: April 16, 2012
Received: April 17, 2012

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113221

Device Name: NAMSA Biological Indicator Spore Strip

Indications for Use: The NAMSA Biological Indicator Spore Strip (single species *Geobacillus stearothermophilus* ATCC® 7953, or dual species *Geobacillus stearothermophilus* ATCC® 7953 and *Bacillus atrophaeus* ATCC® 9372) is intended for use in testing the efficacy of steam sterilization for single species and steam and ethylene oxide sterilization for dual species.

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Prescription Use _____ (Part 21 CFR 801 SubpartD) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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